February 6, 2020

Intuitive Surgical
Brandon Hansen
Manager, Regulatory Submission
1266 Kifer Road
Sunnyvale, California 94086

Re: K191529
Trade/Device Name: da Vinci Xi Surgical System, da Vinci X Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: January 8, 2020
Received: January 9, 2020

Dear Brandon Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jitendra Virani
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191529

Device Name
da Vinci Xi Surgical System - Model IS4000

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Xi Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191529

Device Name
da Vinci X Surgical System (Model IS4200)

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci X Surgical System, Model IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

6 510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Brandon Hansen Manager, Regulatory Submissions Phone Number: 408-523- 7485 Fax Number: 408-523-8907 Email: brandon.hansen@intusurg.com
Date Summary Prepared:	February 04, 2020
Trade Name:	*da Vinci® Xi™* Surgical System *da Vinci® X™* Surgical System
Common Name:	Endoscopic instrument control system
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	*da Vinci® Xi* Surgical System, Model IS4000, *EndoWrist®* Instruments, and Accessories with Remote Software Update (K161271) *da Vinci® Xi™* Surgical System, Model IS4200 (K171294)

Device Description

The subject of this 510(k) submission are software modifications to the *da Vinci* Xi Surgical System (Model IS4000) and *da Vinci* X Surgical System (Model IS4200). These modifications allow Intuitive Surgical to offer cloud-based features to the IS4000 and IS4200 systems such as Surgeon Cloud Accounts, Procedure List, and Central Configuration.

- **Surgeon Cloud Accounts** – Enable surgeons to log in to multiple IS4000 systems and access their personal IS4000 system settings (vision, ergonomic, motion scaling, and energy) by storing user preferences in a cloud-based central Intuitive data server.
- **Procedure List** – Enable surgeons/OR staff to select a surgical procedure they intend to perform from the surgeon console touchscreen before the start of surgery.
- **Central Configuration** – Enable authorized Intuitive Surgical employees to remotely configure features of one or more IS4000 systems simultaneously.

Intended Use/Indications for Use:

Indications for Use statement – da Vinci Xi Surgical System, Model IS4000

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Xi Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Indications for Use statement – (*da Vinci* X Surgical System, Model IS4200)

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* X Surgical System, Model IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Technological Characteristics:

In terms of intended use, indications for use, and fundamental scientific technology, the software modifications to the subject *da Vinci Xi* Surgical System is substantially equivalent to the currently marketed *da Vinci Xi* Surgical System device with Remote Software Update, cleared under K161271. The software modifications introduce new network-based features such as Surgeon Cloud Accounts, Procedure List, and Central Configuration. However, these changes do not alter the intended use of the subject device.

Performance Data:

Using an ISO 14971 compliant risk management process, a comprehensive hazard analysis of the software was performed, and impacted risks assessed, mitigations were evaluated and tested to be acceptable through verification and validation testing. The software development process based on ISO 62304 ensured that the software changes were appropriately documented, risk assessed and tested. Design verification tests were performed to verify the proposed software modifications performed as intended. The testing also verified the modifications to the da Vinci system software and server infrastructure did not raise new questions of safety and effectiveness. In addition, the pre and

postmarket FDA guidance documents regarding cybersecurity were followed to document, risk assess and verify that the cybersecurity controls performed as expected in the event of an exploitation of a cybersecurity vulnerability. Performance test data demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. None of the software modifications impact the intended use or indications for use of the *da Vinci X/Xi* Systems.

Summary:

The intended use/indications for use remain identical to the predicate devices. Based on the intended use, indications for use, technological characteristics, and performance data, the modified devices (subjects), *da Vinci X/Xi* Surgical Systems with Surgeon Cloud Accounts, Procedure List and Central Configuration are substantially equivalent to the current devices in the market (predicates).